



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,897	04/18/2006	Luigi De Ambrosi	SER-103.0 P US	4476

7590
Leon R Yankwich
Yankwich & Associates
201 Broadway
Cambridge, MA 02139

07/13/2007

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
----------	--------------

1623

MAIL DATE	DELIVERY MODE
-----------	---------------

07/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/555,897

Applicant(s)

DE AMBROSI ET AL.

Examiner

Ganapathy Krishnan

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/07/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The first page of the WIPO document filed 11/07/2005, which has an abstract, has also been used as the abstract sheet in the instant specification. This is not acceptable if the instant claims are determined to be allowable at a later stage. The Office requires the abstract to be typed on a separate sheet of paper even though applicants intend using the abstract on the WIPO document for the instant application. Hence, applicants are requested to kindly type the abstract appearing on the first page of the WIPO document (WO 2004/099256) on a separate sheet and file the same.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1623

Claims 1 and 4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 7,091,337 ('337). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for depolymerization of a glycosaminoglycan comprising exposing the glycosaminoglycan to UV radiation. Dependent claim 4 is drawn to the process wherein the glycosaminoglycan is heparin.

Claim 1 of '337 is also drawn to a process for depolymerization of a glycosaminoglycan via exposure of the glycosaminoglycan to radiation, which reads on UV radiation. Dependent claim 2 of '337 is drawn to the process wherein the glycosaminoglycan is heparin.

It would be obvious to one of ordinary skill in the art at the time the invention that instant claims 1 and 4 are substantially overlapping with those of claims 1-2 of '337. Instant claims 1 and 4 should recite limitations that are patentably distinct from those of claims 1-2 of '337. Similarity in structure, process steps and end results entails motivation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-7 is rejected under 35 U.S.C. 102(b) as being anticipated by Balazs et al (Radiation Research, 1959, 11, 149-164; document # CA in IDS of 11/07/2005).

Art Unit: 1623

Balazs et al teach the depolymerization of hyaluronic acid (glycosaminoglycan) via irradiation of the hyaluronic acid with UV radiation from a low-pressure mercury lamp (UV radiation emitted at 253nm; limitations of claims 1-3; page 150, paragraph 4). The hyaluronic acid used as starting material had a molecular weight of 80,000 and the molecular weight of the depolymerized hyaluronic acid obtained was 19,700 (M_w less than 50% of the M_w of the starting glycosaminoglycan before irradiation; limitation of claims 1 and 7; page 155, first paragraph). The irradiation of the hyaluronic acid was performed below 37°C (page 150, fifth paragraph; limitation of claim 6). Balazs et al also teach that similar results were obtained on irradiating heparin with UV light (page 155, last paragraph; limitation of claim 4).

Claim 7 is a Product-by-Process claim. Product-by-Process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1623

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs et al (Radiation Research, 1959, 11, 149-164; document # CA in IDS of 11/07/2005) in view of Mascellani et al (WO 90/04607; document #BB in IDS of 11/07/2005).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Balazs et al teach the depolymerization of hyaluronic acid (glycosaminoglycan) via irradiation of the hyaluronic acid with UV radiation from a low-pressure mercury lamp (UV radiation emitted at 253nm; page 150, paragraph 4). The hyaluronic acid used as starting material had a molecular weight of 80,000 and the molecular weight of the depolymerized hyaluronic acid obtained was 19,700 (M_w less than 50% of the M_w of the starting glycosaminoglycan before irradiation; page 155, first paragraph). The irradiation of the hyaluronic acid was performed

Art Unit: 1623

below 37°C (page 150, fifth paragraph). Balazs et al also teach that similar results were obtained on irradiating heparin with UV light (page 155, last paragraph). However, Balazs does not teach the depolymerization of dermatan sulfate as instantly claimed.

Mascellani et al teach the depolymerization of dermatan sulfate using chemical depolymerization, which involves further purification (page 12, line 27 through page 13, line 21). However, Mascellani does not teach the depolymerization of dermatan sulfate via UV irradiation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to depolymerize dermatan sulfate via the process as instantly claimed since such a process has been demonstrated for other similar glycosaminoglycans in the prior art.

One of skill in the art would be motivated to depolymerize dermatan sulfate using UV radiation since one of skill in the art would expect depolymerization initiated by UV irradiation to work equally well for dermatan sulfate. Moreover as taught by Balazs (page 162, lines 29-30, 3rd full paragraph) irradiation with UV light produces small dialyzable fractions and hence no extensive purification such as percolation through a resin (example 5) is required. Since the depolymerization can be carried out in an aqueous solution the presence of solvent and other chemical impurities derived from depolymerizing agents are avoided.

Conclusion

Claims 1-7 are rejected


Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623